EXHIBIT 3

Appendix A

Ali M. Afnan, BSc, MSc, Ph.D., CChem, MRSC

President, Step Change Pharma Inc.

ali.afnan@stepchangepharma.com

Employment History

3/2010 to present: President and Founder, Step Change Pharma, Inc.

Regulatory strategist facilitating pharmaceutical performance, product quality and effective GMP remediation

Consulting includes:

- Regulatory compliance remediation
  - Responding with 483 observations, untitled and warning letters
  - Developing and managing remediation programs
  - Data integrity audits and remediation
  - Performing audits for remediation, PAI and GMP inspections (FDA, EMA, WHO)
- Third-party quality and operations oversight to meet regulatory agencies' expectations (FDA, MHRA, WHO and MCC) including batch certification
- Advising, preparing for, and accompanying firms in compliance meetings with regulators
- Overseeing quality and manufacturing operations
- Quality management system development and improvement
- Process Validation and Continued Process Verification (as well as Continuous Process Verification as per EMA regulations)
- Reviewing and assessing regulatory documents, regulatory compliance management
- Implementing process change as well as streamlining regulatory change
- Development and delivery of pharmaceutical excellence, from development to manufacturing and quality assurance
- Facilitating and managing changes in process, practices, and culture
- Assist in preparation and review of NDA, ANDA, BLA and PAS reviews as well as managing the associated processes
- Assisting and advising on regulatory processes for changes to NDA, ANDA, BLA, and MAA
- Developing statistical methods and procedures for meaningful process control
- Facilitating transition to continuous manufacturing by managing and advising on process change and controls, including managing the regulatory interactions
- Subject Matter Expert (SME) supporting litigation and arbitration

5/2003 to 3/2010: Senior Staff Fellow and Science Policy Advisor to Director, Office of Pharmaceutical Science, CDER, FDA, USA. Developing regulatory policy.

- One of the key contributors to the 2011 Process Validation (2011) and Process Analytical Technology (PAT) Guidances;
- Establishing training programs for both drug application reviewers and investigators charged with inspecting pharmaceutical manufacturing facilities (Pharmaceutical Inspector Training);
- Facilitating submission of new and generic drug applications based on PAT & QbD;
- Mentoring staff assigned to review, inspection and compliance issues;
- Coordinating discussions with industry and other regulatory Agencies.

1/1993 to 11/2002: Senior Technologist, International Technology Development Group, Pharmaceutical Engineering, AstraZeneca Plc, UK.

Worked in a multidisciplinary group, across multiple functions worldwide to change development, manufacturing and quality practices. Responsibilities included problem solving, development and implementation of PAT, devising regulatory strategy, undertaking feasibility studies, specification of inspection and analytical equipment, and project management. Led the design and construction of a solid dosage facility exercising total control over manufacturing operations.

9/1989 to 12/1992: Measurement and Control Engineer, On-line Measurement and Control Division, Corporate Engineering, ICI Plc, UK.

Responsibilities included design and manufacture of novel and specific sampling, measurement and control systems; adaptation of existing techniques and instruments to address measurement and control needs of various divisions; all aspects of project management from costing, approving and managing of accounts, negotiations and management of time and people.

5/1989 to 9/1989: Analytical Chemist, Agrochemicals Research, Rhone-Poulenc Rorer Plc, Essex, UK.

7/1983 to 8/1984: Analytical Chemist, Exxon Research and Petroleum Centre, UK (12 month industrial experience as part of the B.Sc. course).

Education

11/1986-4/1989: Ph.D., Thesis: “Programmable Flow Injection Analysis”, Department of Instrumentation and Analytical Science (DIAS), University of Manchester Institute of Science and Technology (UMIST), UK.

10/1985-11/1986: M.Sc., Instrumentation and Analytical Science, DIAS, UMIST.

10/1981-7/1985: B.Sc., Industrial Chemistry, Department of Applied Chemistry, University of Wales Institute of Science and Technology (UWIST), Cardiff, UK.

Affiliations:

- 10/2006 to 10/2010: Adjunct Professor, Graduate School Of Pharmaceutical Sciences, Duquesne, University of Pittsburgh, United States
- The Royal Society of Chemistry: Chartered member (CChem, MRSC)
- Senior Member of American Society for Quality (ASQ)
- 2006 to 2009: Commissioner member of the Pharmaceutical Professional Commission (PCC). The Commission is charged with developing, implementing, and managing the professional certification credential program to serve pharmaceutical professionals.
- 2004 to present: ASTM International: founder member and member of the executive management of technical committee E55.
- 6/2010 to 1/2013: Contributing editor of Pharmaceutical Manufacturing (Print and e-Edition)
- 9/2010 to present: Editorial member of Contract Pharma Magazine.

Awards:

- Awarded the 2012 International Pharmaceutical Federation's IPS Medal for Meritorious Contribution to the global pharmaceutical industry.
- FDA Commissioner's Special Citation, May 6, 2005.
- CDER Center Director's award for "Team Excellence", November 18, 2005
- 2005 CDER Scientific Achievement Award for "Outstanding Intercenter Scientific Collaboration", April 28, 2005
- 2005 FDA Scientific Achievement Award for "Outstanding Intercenter Scientific Collaboration", April 28, 2005
- Pharmaceutical Manufacturing Magazine's "Team of the Year" award, 2005.
- In November 1988 awarded the first prize at the Young Scientists Research Meeting – a jointly organized meeting of The Royal Society of Chemistry and The Chromatographic Society.

Patents:

- US Patent 6,517,230: "Mixing Apparatus and Method", granted February 11, 2003

- US Patent 6,776,517: "Mixing Apparatus and Method", granted August 17, 2004
- US Patent 6,874,928: "Mixing Apparatus and Method", granted April 5, 2005

Publications:

Some of my publications are listed below.

- Contributing editor to the on-line and print versions of Pharmaceutical Manufacturing (June 2010 to present)
- Process Analytical Technology Case Study: Part II. Development and Validation of Quantitative Near-Infrared Calibrations in Support of a Process Analytical Technology Application for Real-Time Release, Robert P. Cogdill, Carl A. Anderson, Miriam Delgado-Lopez, David Molseed, Robert Chisholm, Raymond Bolton, Thorsten Herkert, Ali M. Afnán, James K. Drennen., AAPS PharmSciTech 2005; 6 (2) Article 37 (http://www.aapspharmscitech.org).
- Process Analytical Technology Case Study: Part II. Development and Validation of Quantitative Near-Infrared Calibrations in Support of a Process Analytical Technology Application for Real-Time Release, Robert P. Cogdill, Carl A. Anderson, Miriam Delgado, Robert Chisholm, Raymond Bolton, Thorsten Herkert, Ali M. Afnan, James K. Drennen, AAPS PharmSciTech 2005; 6 (2) Article 38 (http://www.aapspharmscitech.org).
- Next Generation Pharmaceutical: "Quality Counts", issue 143, 2005

  http://www.ngpharma.com/pastissue/article.asp?art=25536&issue=143
- Process Analytical Technology and ASTM Committee E55, Standardization News, Monthly magazine of the ASTM International, may 2004, D. Christopher Watts, Ph.D., Ali M. Afnan, Ph.D., and Ajaz S. Hussain, Ph.D.
  (This article was reprinted in 2006 and published in Chinese)
- AM Afnan, PAT: Harbinger of Change, European Pharmaceutical Review, Vol 10 (2), 2005.
- AM Afnan, "PAT: What's in a Name?", The Journal of Process Analytical Technology, Volume 1 (1)
- AM Afnan, Improved Product Security Using on-line Near Infra-Red Spectroscopy, European Pharmaceutical Review, 2001.

All of my work at AstraZeneca was leading-edge and related to market-sensitive products and or processes leading-edge research. Some of the findings were patented, none published.